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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/761,424	01/22/2004	William J. Carroll	000309-00053	1421
27557	7590	04/19/2007		
BLANK ROME LLP 600 NEW HAMPSHIRE AVENUE, N.W. WASHINGTON, DC 20037			EXAMINER STOKLOSA, JOSEPH A	
			ART UNIT	PAPER NUMBER
			3762	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/19/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.		Applicant(s)	
	10/761,424		CARROLL ET AL.	
	Examiner		Art Unit	
	Joseph Stoklosa		3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 March 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-42 is/are pending in the application.
- 4a) Of the above claim(s) 9-14 and 23-42 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8 and 15-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on _____ is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date: _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date: _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

1. Applicant's election with traverse of Claims 1-8 and 15-22 in the reply filed on 3/12/2007 is acknowledged. The traversal is on the ground(s) that Group II and Group I are not a combination and subcombination. Although applicant cites claim 12 to discredit this, the remaining claims of Group I still do not require the particulars of the combination, such as a field programmable gate array, but also hardwired circuitry. Applicant argues that Group I, II and III are not related as a process and apparatus for its practice stating that the materially different process would not required implanted electrodes, however Examiner takes the position that implantable electrodes are used in brain stimulation systems, as well as pointing out that the restriction requirement is proper so long as it can be shown that the apparatus can practice any other materially different process per MPEP 806.05. In light of the previous arguments the traversal of the restriction is found not to be persuasive.
2. The requirement is still deemed proper and is therefore made FINAL.
3. Claims 9-14 and 23-42 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 3/12/2007.

Response to Arguments

4. Applicant's arguments, see Applicant Arguments/Remarks page 4, filed 11/22/2006, with respect to Claims 1-42 have been fully considered and are persuasive. The rejection of 8/23/2006 has been withdrawn.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1-8 and 15-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
7. Claim 1 and 15, claim connection of electrodes to the patient in line 7, and should be revised to include "adapted to be located..."
8. In Claim 1 it is also unclear whether the Applicant is positively reciting the use of common sine wave generators or not.
9. Claims 2 and 3, claim "approximate a sine-wave-like output waveform," and is unclear whether this is the same sine wave as seen in claim 1, or a separate sine-like waveform.
10. With regard to Claims 8 and 22, it is unclear whether the "two quadripolar leads" are the same two implantable electrodes as seen in Claim 1.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

13. Claims 1-8 and 15-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over King et al. (US 6,505,078) in view of Carter et al (US 2001/0031999).

14. With regards to claims 1, 2, 4, 15, 16, and 18, King et al disclose electrode positioning for inferential stimulation therapies including: an interferential current generator (Col. 6, line 40) with at least two pairs of implantable electrodes (Col. 7, line 1-18, Figs. 16-21) for stimulation of the spinal cord (Col. 4, line 53-54; Fig. 2).

15. King et al fail to teach the use of sinusoidal signals with frequencies of at least 500Hz but no more than 20KHz, and the formation of a beat frequency.

16. Carter et al teach that it is known to use sinusoidal signals with frequencies of at least 500Hz but no more than 20KHz, and formation of a beat frequency as set forth in paragraph 36, to provide for optimal therapeutic effect reference pain suppression. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system as taught by King et al with the use of sinusoidal signals with frequencies of at least 500Hz but no more than 20KHz, and the formation of a beat frequency as taught by Carter et al, since such a modification would provide the system with use of sinusoidal signals with frequencies of at least 500Hz but no more than 20KHz, and the formation of a beat frequency for providing optimal therapeutic benefits for pain suppression.

17. With regards to claim 3 and 17, King in view of Carter discloses inherently a field programmable gate array for controlling and steering the 2 dimensional electrode array embodiment disclosed. A gate array would be inherently included to control the polarities and voltages and combinations of such in order to create the fields configurations provided in figs. 16-22. In the alternative such a modification would have been obvious to one having ordinary skill in the art at the time the invention was made, since field programmable gate arrays were known to provide to enhance digital signals and provide a greater therapeutic combinations through the use of digital logic gates.

18. With regard for claims 5-7 and 19-21, King in view of Carter disclose the claimed invention specifically King discloses varying pulse widths from 50-500 micro seconds, and even a range of 500-2000 (Col. 7, line 51) and voltages less than 11 volts (Figs. 19-21), but fail to teach a pulse width range of as small as 10 microseconds, as well as a

Art Unit: 3762

maximum voltage of 11 volts. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system as taught by King in view of Carter, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum workable ranges involves only routine skill in the art [*In re Aller*, 105 USPQ 233] and/or since it has been held that a prima facie case of obviousness exists where the claimed ranges and prior art ranges do not overlap but are close enough that one skilled in the art would have expected them to have the same properties. *Titanium Metals Corp. of America v. Banner*, 778 F.2d 775, 227 USPQ (Please see MPEP 2144.05).

19. With respect to claim 8 and 22, King in view of Carter discloses the claimed invention except for the use of two quadripolar leads. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system as taught by King in view of Carter with two quadripolar leads since it was known that quadripolar leads are used to provide larger stimulation areas and more flexibility and variance in steering an electrical field.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Stoklosa whose telephone number is 571-272-1213. The examiner can normally be reached on Monday-Friday 7:30-4:00.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571-272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3762

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Joseph Stoklosa
Examiner
Art Unit 3762

JS
4/11/2007


GEORGE R. EVANISKO
PRIMARY EXAMINER

4/16/7